

### DETAILED ACTION

Claims 1-46 and 48 are pending in the application.

This action is in response to applicants' petition filed December 10, 2010.

The petition was granted on January 18, 2011 vacating the final office action of September 30, 2010 and allowing the amendment filed November 24, 2010 to be entered. The following office action is based on the amendment filed November 24, 2010.

### *Response to Amendment*

Applicant's amendments filed November 24, 2010 have been fully considered with the following effect:

1. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 5a), c), d), f), h), i), k), o), p), q), r), s) and t) in the last office action, which are hereby **withdrawn**.
2. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejections labeled paragraph 6) in the last office action, which is hereby **withdrawn**.
3. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 7a), b) and c) in the last office action, which are hereby **withdrawn**.

In view of the amendment dated November 24, 2010, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

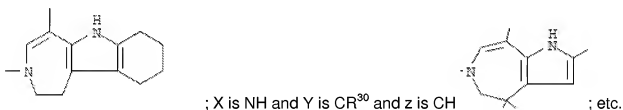
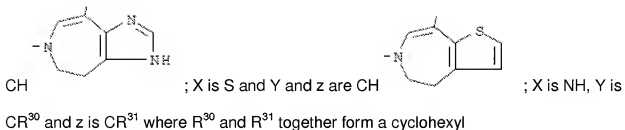
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6, 14-17, 19-22, 24-28, 30, 32, 33, 46 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

HOW TO MAKE: In evaluating the enablement question, several factors are to be considered. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988); *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

Instant claims are rejected because they are not enabled for the scope of the compounds provided by the various values possible for variables X, Y, z, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>5</sup>, R<sup>6</sup>, and R<sup>7</sup> in formula (I). Said variables are not fully defined and thus embrace an assortment of moieties limited only by the imagination of the skilled artisan and for which there is no reasonable enablement nor disclosure of starting materials thereof.

Note *Ex parte Moersch*, 104 USPQ 1122; *In re Howarth*, 210 USPQ 689; *In re Lund*, 153 USPQ 625; and *In re Wiggins*, 179 USPQ 421. Compounds made and tested are directed to a much narrower scope than that being claimed, i.e. X and z are NH and Y is



Note *In re Surrey*, 151 USPQ 724 regarding the sufficiency of disclosure for a Markush group in cases directed to structure-sensitive arts. Thus there is no reasonable basis for assuming that the body of compounds claimed would all share the minimum requisite activities since they are so structurally dissimilar as to be chemically inequivalent and there is no basis in the prior art for assuming the same.

The magnitude of possible ring systems are not described in the disclosure in such a way the one of ordinary skill in the art would know how to prepare the various compounds suggested by claims 1-6, 14-17, 19-22, 24-28, 30, 32, 33, 46 and 48. For example where are the starting materials for the preparation of compounds where ring X is O, Y is N and Z is N, etc. In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples, and the general unpredictability of chemical reactions, it would take an undue amount of

experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention.

The instant specification teaches about 13 examples where X, Y and z of formula I forms an imidazo[4,5-d]azepine, azepino[4,5-b]indole, thieno[2,3-d]azepine and pyrrolo[2,3-d]azepine.

In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples, and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention. To be enabling, the specification of a patent must teach those skilled in the art how to make and use the scope of the claimed invention without undue experimentation. The applicants' are not entitled to preempt the efforts of others. The test for determining compliance with 35 U.S.C. § 112, is whether the applicants have clearly defined their invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8, 10-17, 19-22, 24-28, 30-42, 44, 46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of  $R^{77}$  where there is no variable  $R^{77}$  in the claim. (Claims 1-8, 10-17, 19-22, 24-28, 30, 32, 33 and 48)
- b. Claim 6 and claims dependent thereon recites the limitation " $R^{33}$ ,  $R^{34}$ " in last line of the claim. There is insufficient antecedent basis for this limitation in the claim.
- c. Claim 8 and claims dependent thereon recites the limitation " $R^{33}$ ,  $R^{34}$ " in last line of the claim. There is insufficient antecedent basis for this limitation in the claim.
- d. Claim 12 and claims dependent thereon recites the limitation " $R^{33}$ ,  $R^{34}$ " in last line of the claim. There is insufficient antecedent basis for this limitation in the claim.
- e. Claim 14 and claims dependent thereon recites the limitation " $R^{33}$ ,  $R^{34}$ " in last line of the claim. There is insufficient antecedent basis for this limitation in the claim.
- f. Claim 15 and claims dependent thereon recites the limitation " $R^{33}$ ,  $R^{34}$ " in last line of the claim. There is insufficient antecedent basis for this limitation in the claim.
- g. Claim 17 and claims dependent thereon recites the limitation " $R^{33}$ ,  $R^{34}$ " in last line of the claim. There is insufficient antecedent basis for this limitation in the claim.

- h. Claim 21 and claims dependent thereon recites the limitation "R<sup>33</sup>, R<sup>34</sup>" in last line of the claim. There is insufficient antecedent basis for this limitation in the claim.
- i. Claim 27 and claims dependent thereon recites the limitation "R<sup>33</sup>, R<sup>34</sup>" in last line of the claim. There is insufficient antecedent basis for this limitation in the claim.
- j. Claim 30 recites the limitation "Claim 29" in the first line of the claim. Claim 29 contains two species. There is insufficient antecedent basis for this limitation in the claim.
- k. Claim 30 and claims dependent thereon recites the limitation "R<sup>33</sup>, R<sup>34</sup>" in last line of the claim. There is insufficient antecedent basis for this limitation in the claim.
- l. Claim 31 recites the limitation "4,4-dimethyl" in the species. There is insufficient antecedent basis for this limitation in the claim.
- m. Claim 34 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of R<sup>77</sup> where there is no variable R<sup>77</sup> in the claim. (Claims 34-42 and 44)
- n. Claim 46 is vague and indefinite in that it is not known what is meant by the definition of R<sup>77</sup> where there is no variable R<sup>77</sup> in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Janssen et al., U.S. Patent No. 5,461,050. Janssen teaches the compounds of the instant invention where  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^6$  and  $R^7$  are H; X is S; Y is  $CR^{30}$  where  $R^{30}$  is H; Z is  $CR^{31}$  where  $R^{31}$  is H;  $R^4$  and  $R^5$  together form an optionally substituted imino, i.e.  $=NH$  or  $=NCH_2CH(OCH_3)_2$  as set forth in example 5, lines 26 and 30-31 of column 38.

### ***Claim Objections***

7. Claims 1, 5, 39 and 46 are objected to because of the following informalities:
- a. In Claim 1 formula (I) contains a lower case z and the definition in the claim is to an upper case Z.
  - b. In Claim 5 there is a period located after the definition of  $R^4$ ,  $R^5$ ,  $R^6$  and  $R^7$  labeled paragraph d).
  - c. In Claim 39 there is a period located after the definition of  $R^4$ ,  $R^5$ ,  $R^6$  and  $R^7$  labeled paragraph d).
  - d. In Claim 46 formula (I) contains a lower case z and the definition in the claim is to an upper case Z.
- Appropriate correction is required.
8. Claims 9, 18, 23, 29, 43 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all

of the limitations of the base claim and any intervening claims. None of the prior art of record or a search in the pertinent art area teaches the species as claimed herein.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENDA COLEMAN whose telephone number is (571)272-0665. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624